physiological sample.

24. (Once Amended) A kit for use in determining the concentration of an analyte in a physiological sample, said kit comprising:

(a) a storage stable reagent test strip comprising:

(i) a positively charged porous matrix; and

(ii) a peroxide producing signal producing system present on said matrix, wherein said peroxide producing signal producing system includes a urea derivative dye,

wherein said test strip is stable for at least about six months at temperatures ranging from at least about -80°C to 60°C under humidity ranging from at least about 0% to 20%; and

(b) at least one of:

(i) a means for obtaining said physiological sample and

(ii) an analyte standard.

REMARKS UNDER 37 CFR § 1.111

Formal Matters

Claims 1-27 are pending after entry of the amendments set forth herein.

Claims 1-27 were examined and were rejected.

Please replace Claims 1, 11, 14, 19, 20, and 24 with the clean version provided above.

Claims 1, 11, 14, 19, 20, and 24 have been amended. Specifically, Claims 1, 11, 19, 20, and 24 have been amended to specify that the claimed composition of matter or reagent test strip is stable for at least about six months at temperatures ranging from at least about -80°C to 60°C under humidity ranging from at least about 0% to 20%. Support for this amendment is found throughout the specification, and in particular at: page 9, line 27 through page 10, line 7. Claim 14 has been amended solely to correct a typographical error.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached is captioned **"VERSION WITH MARKINGS TO SHOW CHANGES MADE."**

Applicants respectfully request reconsideration of the application and allowance of the pending claims in view of the amendments and remarks made herein.

No new matter has been added by the amendments and their entry by the Examiner is respectfully requested.

Rejection under 35 U.S.C. §102(e)

Claims 1-23 have been rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 5,972,294 issued to Smith et al. The Office Action contends that Smith et al. discloses a reagent test strip comprising a polysulfone membrane, 10-(carboxymethylaminocarbonyl)-3,7-bis(dimethylamino)phenothiazine, glucose oxidase and horse radish peroxidase.

It is well established that a claim is anticipated only if each and every element as set forth in the claim is found in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987), *cert. denied*, 481 U.S. 1052 (1987). *See also Scripps Clinic and Research Foundation v. Genentech, Inc.*, 18 USPQ 2d 1001 (Fed. Cir. 1991). As amended, the claims all specify that the composition of matter or reagent test strip is stable for at least about six months at temperatures ranging from at least about -80°C to 60°C under humidity ranging from at least about 0% to 80%.

Smith et al. simply describes reagent test strips comprising a polysulfone membrane, 10-(carboxymethylaminocarbonyl)-3,7-bis(dimethylamino)phenothiazine, glucose oxidase and horse radish peroxidase, and various methods for their use. Smith et al. also states that polysulfones and polyamides (nylons) are examples of suitable matrix materials (col. 6, line 29-30).

Nowhere does the patent teach or suggest that any test strips are storage stable for at least about six months at temperatures ranging from at least about -80°C to 60°C under humidity ranging from at least about 0% to 20%.

Since Smith et al. does not teach or suggest a storage stable composition of matter or reagent test strip as claimed, Smith et al. does not anticipate the present invention. Accordingly, this rejection of Claims 1-23 under 35 U.S.C. §102(e) should be withdrawn.

Rejection under 35 U.S.C. §103(a)

Claims 24-27 have been rejected under 35 U.S.C. §103(a) as obvious over Smith et al. The Office Action asserts that, while Smith et al. does not expressly disclose, among other things, a kit comprising a reagent test strip, a means for obtaining a blood sample and an analyte standard, it would have been obvious to one having ordinary skill in the art to include such items in a single package.

The law is clear that to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones,* 21 USPQ2d 1941 (Fed. Cir. 1992). Second, there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 231 USPQ 375 (Fed. Cir. 1986). Finally, the prior art reference, or references when combined, must teach or suggest all the claim limitations. *In re Royk*a, 180 USPQ 580 (CCPA 1974).

The deficiency of Smith et al. is described above. Since Smith et al. does not teach or suggest storage stable reagent test strips which are stable for at least about six months at temperatures ranging from at least about -80°C to 60°C under humidity ranging from at least about 0% to 20%, it would not have been obvious to the skilled artisan to include such test strips in a kit as claimed.

Since Smith et al. does not teach or suggest storage a storage stable composition of matter or reagent test strip as claimed, Smith et al. cannot render the present invention obvious. Accordingly, this rejection of Claims 24-27 under 35 U.S.C. §103(a) should be withdrawn.

Conclusion

In view of the above remarks, this application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issue.

If the Examiner finds that a Telephone Conference would expedite prosecution of this application, he is invited to contact the undersigned (650) 327-3400.

In the event that the transmittal letter is separated from this document and the Patent Office determines that extensions or other relief is required and/or fees are due applicants, the Applicant petitions for any required relief, including extensions of time, and authorize the Commissioner to charge our Deposit Account No. 50-0815, Order Number LIFE008, for any fees due in connection with the filing of this document. The Patent Office is not authorized to charge issue fees to our Deposit Account.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: 12.20.01

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claims 1, 11, 14, 19, 20, and 24 have been amended as follows.

1. (Amended) A storage stable composition of matter comprising:

a positively charged porous matrix; and

a urea derivative dye on at least one surface of said matrix,

wherein said composition is stable for at least about six months at temperatures ranging from at least about -80°C to 60°C under humidity ranging from at least about 0% to 20%.

11. (Once Amended) A storage stable reagent test strip for use in detecting the presence or determining the concentration of an analyte in a physiological sample, said strip comprising:

a positively charged porous matrix; and

a peroxide producing signal producing system present on said matrix, wherein said peroxide producing signal producing system includes a urea derivative dye,

wherein said test strip is stable for at least about six months at temperatures ranging from at least about -80°C to 60°C under humidity ranging from at least about 0% to 20%.

14. (Once Amended) The test strip according to Claim 11, wherein said urea derivative dye has the formula:

$R^1R^2NCONHR^3$, wherein R^1 , R^2 taken together is a N, N-di-substituted aminoaryl, and R^3 is selected from the group consisting [ofcarboxyalkyl] of carboxyalkyl, alkoxycarbonyl, alkylcarbonyl, arylsulfonyl, sulfoaryl and carboxyaryl

19. (Once Amended) An analyte detection or measurement system comprising:

(a) a storage stable reagent test strip comprising:

(i) a positively charged porous matrix; and

(ii) a peroxide producing signal producing system present on said matrix, wherein said peroxide producing signal producing system includes a urea derivative dye; and

(b) an automated instrument,

wherein said test strip is stable for at least about six months at temperatures ranging from at least about -80°C to 60°C under humidity ranging from at least about 0% to 20%.

20. (Once Amended) A method for detecting the presence or determining the concentration of an analyte in a sample, said method comprising:

(a) applying said physiological sample to a storage stable reagent test strip comprising:

(i) a positively charged porous matrix; and

(ii) a peroxide producing signal producing system present on said matrix, wherein said peroxide producing signal producing system includes a urea derivative dye,

wherein said test strip is stable for at least about six months at temperatures ranging from at least about -80°C to 60°C under humidity ranging from at least about 0% to 20%;

(b) detecting a signal produced by said signal producing system; and

(c) relating said detected signal to the presence or concentration of said analyte in said physiological sample.

25. (Once Amended) A kit for use in determining the concentration of an analyte in a physiological sample, said kit comprising:

(a) a storage stable reagent test strip comprising:

(i) a positively charged porous matrix; and

(ii) a peroxide producing signal producing system present on said matrix, wherein said peroxide producing signal producing system includes a urea derivative dye,

wherein said test strip is stable for at least about six months at temperatures ranging from at least about -80°C to 60°C under humidity ranging from at least about 0% to 20%; and

(b) at least one of:

(i) a means for obtaining said physiological sample and

(ii) an analyte standard.